




# Essai Clinique

Généré le 13 mai 2024 à partir de

Titre	Primary Thromboprophylaxis in Patients With Malignancy and Central Venous Catheters: a Randomized Controlled Trial
Protocole ID	TRIM-Line 3698
ClinicalTrials.gov ID	<a href="#">NCT05029063</a>
Type(s) de cancer	Contrôle des symptômes
Type étude	Support
Médicament	Rivaroxaban 10 MG
Institution	CISSS DE CHAUDIERE-APPALACHES  HOTEL-DIEU DE LEVIS 143 rue Wolfe, Lévis, QC, G6V 3Z1
Ville	
Investigateur principal	Dr Frédéric Larose
Coordonnateur	Pierre Bédard 418-835-7121
Statut	Actif en recrutement
Date d'activation	16-11-2023
But étude	The purpose of the full trial is to determine the efficacy and safety of prophylactic dose rivaroxaban to prevent VTE among cancer patients with CVC.
Critères d'éligibilité	<ul style="list-style-type: none"><li>• Patients 18 years of age or older with a new or existing diagnosis of cancer and a CVC inserted in the last 72 hours.</li></ul>
Critères d'exclusion	<ul style="list-style-type: none"><li>• CVC in place for &gt;72 hours</li><li>• Patient requires anticoagulation for other indications</li><li>• Concomitant use of dual antiplatelet therapy</li><li>• Major bleeding event in the last 4 weeks</li><li>• Patients receiving concomitant systemic treatment with strong inhibitors of both CYP 3A4 and P-gp (such as cobicistat, ketoconazole, itraconazole, posaconazole, or ritonavir).</li><li>• Known pregnancy or plan to become pregnant in next 3 months</li><li>• Severe renal insufficiency (Creatinine clearance &lt;30 mL/min (defined by Cockcroft-Gault) in the previous 3 months</li><li>• Documented severe liver disease (e.g., acute clinical hepatitis, chronic active hepatitis or cirrhosis) in the previous 3 months</li><li>• Known thrombocytopenia (platelet count &lt; 50x 10<sup>9</sup>/L) in the previous 3 months</li><li>• Known allergy to rivaroxaban</li><li>• Life expectancy &lt;3 months</li><li>• History of condition at increased bleeding risk including, but not limited to:<ul style="list-style-type: none"><li>• cerebral infarction (hemorrhagic or ischemic), active peptic ulcer disease with recent bleeding, spontaneous or acquired impairment of hemostasis in the past 4 weeks.</li><li>• Chronic hemorrhagic disorder</li></ul></li><li>• Primary malignancy diagnosis of basal cell or squamous cell carcinoma of the skin only</li><li>• Refused or unable to obtain consent</li></ul>